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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,839	06/21/2002	Marie Flamand	03495.0213	3749
22852	7590	05/28/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			STUCKER, JEFFREY J	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,839

Applicant(s)

FLAMAND ET AL.

Examiner

Jeffrey Stucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2004 and 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30 and 43-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30 and 43-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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This Office Action is in response to the RCE filed 5/4/04 and the entry of the after final amendment filed 2/15/04. Claims 27-30 and 43-52 are pending and rejected.

The rejection of claims 27-30 and new claims 43-52 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained**. Even though the revelation antibody would be specifically recited as being labeled, this does not preclude the first antibody from being labeled, thereby not distinguishing them.

The rejection of claims 27-30 under 35 U.S.C. § 103(a) as obvious over the admissions in the specification in view of both Zuk et al. (US 4281061) and Crooks et al. (J. of Gen. Vir., 1994) is withdrawn because the art does not teach or suggest antibodies with high affinity binding for hexameric NS1.

The rejection of claim 38 under 35 U.S.C. § 103(a) as obvious over the admissions in the specification in view of both Zuk et al. (US 4281061) and Crooks et al. (J. of Gen. Vir., 1994) further in view of Harlow et al. is withdrawn because the art does not teach or suggest antibodies with high affinity binding for hexameric NS1.

The rejection of claim 27 under 35 U.S.C. § 103(a) as obvious over the admissions in the specification in view of both Zuk et al. (US 4281061) and Crooks et al. (J. of Gen. Vir., 1994) further in view of Harlow et al. is withdrawn because the art does not teach or suggest antibodies with high affinity binding for hexameric NS1.

The rejection of claim 27 under 35 U.S.C. § 103(a) as obvious over the admissions in the specification in view of both Zuk et al. (US 4281061) and Crooks et al. (J. of Gen. Vir., 1994) further in view of Tijssen is withdrawn because the art does not teach or suggest antibodies with high affinity binding for hexameric NS1.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed, specifically, antibodies rather than antigen, *per se*.

The following are new grounds of rejection:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-30 and 43-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because of the new phrase “comprising an assay”. An assay is a test, analysis, or examination of some characteristic(s). This rejection would be obviated by amending the term so assay components, reagents, or similar. Applicant is cautioned about adding new matter and is required to point to support in the specification for any amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to, and the claims are rejected, under 35 U.S.C. §112, first paragraph, as failing to provide an adequate teachings of enablement and failing to provide a best mode of carrying out the invention.

The claimed antibodies are biological materials necessary to practice the claimed invention as the starting material and the product claimed *per se* in the claims are necessary to practice the invention. Because it does not appear that the hybridomas or monoclonal antibodies are known and publicly available or can be reproducibly isolated from nature without undue experimentation, deposit of the hybridoma cell line is required. Without a publicly available deposit of the cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event. Mere description of the cell line is not adequate, due to its taxonomic incompleteness and inexactness. Note that the best mode is not satisfied by a written disclosure unless that exact embodiment is absolutely reproducible from that disclosure. If reproducibility of the cell line is not established, failure to deposit the cell line would result in the quality of applicant's best mode disclosure to be so poor as to effectively result in concealment of the best mode contemplated by applicant for carrying out the invention. *In re Sherwood*, 615 F.2d 809, 204 USPQ 537 (CCPA 1980). Applicant is reminded that the deposit of biological material is a recognized exception to the requirement for a written disclosure only where applicant was unaware of repeatable process to obtain this material at the time the application was filed.

There is no evidence of record that the mouse hybridomas and monoclonal antibodies may be reproducibly produced without undue experimentation or that a suitable deposit has been made for patent purposes. The specification lacks complete deposit information for the deposit. Applicant's referral to a deposit in the specification is an insufficient assurance that all required deposits have been made and the conditions of 37 CFR 1.801-1.809 met.

If deposits have been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that each deposit has been accepted by an

International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to each deposits will be irrevocably removed upon the grant of a patent on this application and that each deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits for U.S. patent purposes, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicant or assignees or in the form of a statement by an attorney of record who has authority and control over the conditions of deposit, over his or her signature and registration number, averring:

(a) during the pendency of this application, access to each deposit will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

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(c) each deposit will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) each deposit will be replaced if it should become nonviable or non-replicable.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

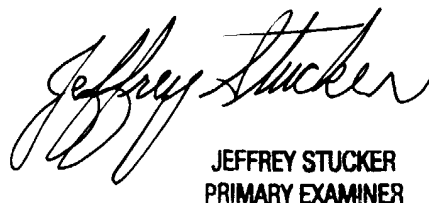
The Group 1600 Official Fax number is: (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.



JEFFREY STUCKER
PRIMARY EXAMINER